

developed in NSCLC, has been established here in SCLC. Patients on amrubicin experienced less symptom deterioration during treatment.

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LESSONS LEARNED FROM HTA COST EFFECTIVENESS EVALUATIONS OF NEW CASTRATION-RESISTANT PROSTATE CANCER MEDICATIONS

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OBJECTIVES: Gain insights into Health Technology Assessment (HTA) agencies expectations regarding Health-Related Quality of Life (HRQoL) for cost-effectiveness evaluations of new medications for treating Castration-Resistant Prostate Cancer (CRPC). **METHODS:** In January 2012, 61 HTA agencies websites were scanned to identify HTAs of new medications for the treatment of CRPC published from 2005 to present. Only those evaluating the cost-effectiveness of new technologies were retained and analyzed for a better understanding of HTA agencies' expectations regarding HRQoL in CRPC. **RESULTS:** 39 HTAs were identified, 12 of which are currently in progress. The 27 published reports comprised 12 technology appraisals, 9 horizon scanning reports and 6 literature reviews. Only 9 of the 12 technology appraisals evaluated cost-effectiveness, these included seven appraisals on three drugs: IQWiG (Germany) assessed abiraterone; NICE (England & Wales) accepted docetaxel and rejected cabazitaxel; SMC (Scotland) rejected docetaxel and cabazitaxel; CVZ (Netherlands) accepted cabazitaxel; PBAC (Australia) accepted docetaxel after two rejections and rejected cabazitaxel. Uncertainty regarding HRQoL measures was the most often cited negative comment. For both docetaxel and cabazitaxel, the absence of quality of life measures from the main phase III trials and uncertainty around utility values were cited as reasons for rejection by NICE, SMC and PBAC. The CVZ accepted cabazitaxel for temporary reimbursement on the understanding that further subpopulation analysis and more data on utilities will be needed. The IQWiG assessment of abiraterone commented on uncertainties regarding the validity of the QoL questionnaire and restrictions in subgroup analyses. **CONCLUSIONS:** Our review indicates the need to include comprehensive quality of life measures in phase III trials for new drugs to treat CRPC, ensure these can be mapped into robust utility values and conduct meaningful CRPC subpopulation analyses. Further insights will be gained in the near future with the publication of CRPC HTAs currently in progress.

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PATIENT REPORTED OUTCOMES IN ONCOLOGY CLINICAL TRIALS: ARE YOU CAPTURING THE LINGUISTIC DIVERSITY OF THE PATIENT POPULATION IN INDIA?

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OBJECTIVES: Data collected using patient reported outcomes (PRO) tools in clinical trials provide unique information about patients' experience with their treatment. One of the major challenges with conducting clinical trials in linguistically diverse countries such as India, however, is identifying and using PRO scales that are linguistically validated in most of the representative regional languages. Lack of availability of linguistically validated scales can limit the participation of a relevant population from clinical trials. Therefore, the objective of this study was to determine if the PRO instruments used in clinical trials are linguistically validated in local languages across the various regions in India. For this study we limited our therapeutic area focus to clinical trials conducted in oncology. **METHODS:** A detailed review of the registered trials in clinicaltrials.gov was conducted using quality of life (QoL) and oncology as key words. Identified articles (n=103) were screened to exclude trials where QoL was not measured and studies with n < 30. ProQoLID and official websites of questionnaires were used to determine the availability of translations and linguistic validity of the questionnaires included in clinical trials. **RESULTS:** EQ-5D is the most commonly used generic instrument in oncology trials and is validated in most 11 Indian languages. EORTC-QLQC30, EORTC-QLQH&N35, EORTC-QLQBR23 and EORTC-QLQLC13 are the most commonly used cancer specific instruments and are validated in approximately 10 Indian languages. None of the generic or disease specific cancer instruments have been translated or linguistically validated for the Eastern & North-Eastern regions in India in languages such as Oriya, Santhali, Assamese, and Manipuri thereby limiting the participation of patients from these regions in clinical trials. **CONCLUSIONS:** The results of our analysis indicate that future efforts need to focus on translating and validating PRO instruments in 14 different Indian languages that should include the North Eastern regions of India.

CANCER – Health Care Use & Policy Studies

PCN114

USE OF ANTIDEPRESSANTS AMONG INDIVIDUALS WITH CANCER: A SYSTEMATIC REVIEW

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OBJECTIVES: Antidepressants (ADs) are primarily used to treat depression and anxiety among individuals with cancer and depression; however ADs are also being used for symptomatic relief from hot-flashes, neuropathic-pain, and fatigue in this population. Although there is a lack of robust evidence on the effectiveness of ADs in this population, and conflicting reports of a possible association between AD use and risk of recurrence of certain cancers exists; ADs are still being prescribed in this population. Thus, the objective of this study was to systematically review the extent of any AD use among individuals with cancer. **METHODS:** A systemic literature search was con-

ducted using 4 electronic databases (PubMed, CINHAL, PsychINFO, and Web-of-Science), and cross-referencing. Studies starting from 1975 to 2011, and from all countries were assessed. Eligibility criteria used for the extraction of studies included: 1) full articles published in peer-reviewed journals in English-language only; 2) observational studies with data on any use or prescription of ADs; and 3) adults and children aged >1 year diagnosed with cancer (all types and stages of cancer were included). Studies on the use of psychotropic agents other than ADs or psychotherapy were excluded. After data extraction, number and percentages of individuals with cancer using ADs were calculated. **RESULTS:** The search yielded 1880 studies, 14 of which met the predefined inclusion criteria. Overall, the rates of AD use ranged from <1%-26% in varying subgroups of cancer patients; with lower rates in pediatric cancer patients (7%-12.3%), and in those with advanced-stage cancers (7.4%-16%). Rates also varied according to the type of cancers: breast (11.5%-34%), prostate (7%-18.8%), colon (7.5%-17.3%) and lung (7.2%-13.7%). The rates were higher among individuals with cancer and clinically diagnosed depression (12%-66.6%). **CONCLUSIONS:** Our descriptive results suggest that AD use may be associated with cancer site and stage, and presence of clinically diagnosed depression; and is lower in pediatric and advanced-stage cancer patients.

PCN115

PATTERNS OF CARE IN PATIENTS WITH MYELODYSPLASTIC SYNDROMES TREATED WITH HYPOMETHYLATING AGENTS

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OBJECTIVES: Hypomethylating agents (HMAs), decitabine and azacitidine, are indicated for use in treatment of myelodysplastic syndromes (MDS), however only a minority of patients receive HMAs. Our objective was to examine patterns of treatment associated with FDA-approved 5-day decitabine (DEC-5) and 7-day azacitidine (AZA-7) and off-label 5-day azacitidine (AZA-5) in MDS patients. **METHODS:** We identified MDS patients with an initial HMA treatment between July 1, 2005 to June 30, 2009 in 2 large insurance claims databases. Index date was the date of initial HMA treatment. Patients were stratified into: DEC-5, AZA-7, or AZA-5, based on their first cycle of treatment and were followed for 6 months. We described the number of unique cycles of index treatment and treatment gaps (days of missed treatment) in these groups. **RESULTS:** We identified 18,706 patients with MDS; 546 were treated with HMAs and were included in the study (156 received DEC-5, 176 received AZA-5 and 214 received AZA-7). Mean age was similar across groups: 68.8-71.2 years. Neutropenia was more common before treatment initiation in the DEC-5 (34.6%) group than in AZA-5 (22.7%) and AZA-7 (26.6%; p<.05) groups. There were 1,701 treatment cycles: 431 DEC-5 (per patient mean:2.8; median:2), 586 for AZA-5 (mean:3.3; median:3), and 684 for AZA-7 (mean:3.2; median:3) (p<0.05 for means). DEC-5 cycles had the fewest gaps: 94.9% had no treatment gaps, compared to 89.1% for AZA-5 and 23.4% for AZA-7. Among DEC-5 cycles, 3.2% had a 2 day gap, compared to 7.2% for AZA-5 and 66.5% for AZA-7 (p<0.001). **CONCLUSIONS:** In this retrospective claims analysis, few MDS patients were treated with HMAs. Among those who received HMAs, decitabine patients were more likely to have prior neutropenia. Between the 2 FDA-approved regimens, DEC-5 and AZA-7, there were significantly fewer gaps with decitabine treatment. More treatment gaps were observed with use of longer AZA regimen.

PCN116

USING THE MODIFIED RAND/UCLA DELPHI PROCESS TO PRODUCE TREATMENT CONSENSUS IN UNRESECTABLE MIDGUT GASTROINTESTINAL NEUROENDOCRINE TUMORS

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OBJECTIVES: Comprised of carcinoid and pancreatic neuroendocrine tumors (NETs), gastrointestinal NETs give rise to diverse clinical syndromes. Current treatment guidelines lack some specificity. We summarize an expert panel consensus on medical treatment of well-differentiated (grade 1-2) unresectable midgut NETs. **METHODS:** The modified RAND/UCLA Delphi process was used to collect NET treatment appropriateness ratings. The process involved recruitment of physician experts (e.g., by specialty, geography, practice), literature review, and collection of ratings before and after a face-to-face discussion. Experts and moderator were blinded to funding source. Patient scenarios were rated on a 1-9 scale on appropriateness of various therapies and were labeled as appropriate, inappropriate, or uncertain. Scenarios with >2 ratings in 1-3 and >2 in 7-9 range were considered to have disagreement. **RESULTS:** Panelists (age: 38-63 years) were from northeast, midwest, south, and west regions. Panelists had practiced for a mean 15.5 years and reported seeing 25 to 800 NET patients per year. Panelists rated 202 scenarios in midgut NETs. The proportion on which there was disagreement decreased from 11.7% (23 scenarios) before the meeting to 4.5% (9) after. After the meeting, 49% (99 scenarios) were rated inappropriate, 29.7% (60) were uncertain, and 16.8% (34) were appropriate. Resulting consensus statements include: 1) it is appropriate to use somatostatin analogs as 1st-line therapy in all patients; 2) it is appropriate to in-